

# Exhibit 31

1           IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE DISTRICT OF NEW JERSEY  
3                           CAMDEN VICINAGE  
4                               -   -   -

5           IN RE:    VALSARTAN,                   :   MDL NO. 2875  
6           LOSARTAN, AND                        :  
7           IRBESARTAN PRODUCTS                :   CIVIL NO.  
8           LIABILITY LITIGATION                :   19-2875  
9   :   (RBK/JS)

10   :  
11           THIS DOCUMENT APPLIES               :   HON. ROBERT  
12           TO ALL CASES                         :   B. KUGLER  
13                   - CONFIDENTIAL INFORMATION -  
14                   SUBJECT TO PROTECTIVE ORDER

15                               -   -   -  
16                               May 7, 2021  
17                               -   -   -

18                   Videotaped remote deposition of  
19           LANCE R. MOLNAR, Ph.D., taken pursuant to  
20           notice, was held via Zoom  
21           Videoconference, beginning at 9:03 a.m.,  
22           EST, on the above date, before Michelle  
23           L. Gray, a Registered Professional  
24           Reporter, Certified Shorthand Reporter,  
             Certified Realtime Reporter, and Notary  
             Public.

                             -   -   -  
25                   GOLKOW LITIGATION SERVICES  
26           877.370.3377 ph | 917.591.5672 fax  
27                               deps@golkow.com

1 Q. Understood. Okay. So let  
2 me see if I get this straight.

3 So if something is -- so  
4 you're saying that threshold versus  
5 non-thresholded is a function of how a  
6 particular genotoxic compounds exerts its  
7 toxicity?

8 A. It doesn't have to be just  
9 genotoxic. It's just how the -- the  
10 mechanism through which a compound exerts  
11 its toxicity, yes. Or its beneficial  
12 effects. It doesn't matter. I think  
13 that's what a threshold is, right. So...

14 Q. Right. So what does it mean  
15 for a -- in the context of a genotoxic  
16 compound for it to be non-threshold?

17 A. Well, something that doesn't  
18 exist. That's kind of what I'm pointing  
19 out is there's no such thing as a -- that  
20 I know of, or that we know of, that is a  
21 non-thresholded effect; i.e., a  
22 non-threshold effect would mean that a  
23 single molecule could be detrimental,  
24 right? There's no threshold of exposure

1 You can treat them however you want.

2 The EMA, FDA, ICH, you know,  
3 regulatory bodies in general, have  
4 decided that that's how they are going to  
5 treat them. That's their expectations  
6 for deriving limits for them will be.

7 I think the first kind of --  
8 what's the word? The first guidance  
9 document to that effect is the one that  
10 you have on the screen now, from the EMA,  
11 and that approach to consider them non --  
12 as being a non-thresholded mechanism has  
13 continued to this point.

14 Q. And so -- okay. Thank you  
15 for that.

16 And so for -- back to this  
17 guidance document and the statement that  
18 nitrosamines are of such high potency  
19 that they have to be excluded from the  
20 TTC approach.

21 What do you understand that  
22 to mean?

23 MR. TRISCHLER: Objection to  
24 form.